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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,101	03/05/2002	Jean-Marc Zuccarelli	C1190/20007	2827

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,101	ZUCCARELLI ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 12/04/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 10-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Carli et al (USPN 5,725,824 hereafter '824), Dunn et al (USPN 4,308,251 hereafter '251) and Myers et al (USPN 5,733,577 hereafter '577). Claims 10 – 16 are drawn to ibuprofen particles that are coated with cellulose derivatives and colloidal silica. The claims recite specific concentrations of each coating component in relation to the ibuprofen, and the other components. The particles further include other excipients including surfactants, alkali metals, glycerides, and starches. Claims 17,18, 20 and 21 are drawn to a process of making the particles where the pH is maintained by a buffer and a particular level, while the temperature of the drug is maintained below 35 degrees Celsius. The process recites that the particles are below 100 microns. The claims also recite that the granulation and coating occur at the same time.

'824 teaches a dosage form comprising granules of ibuprofen coated in cellulose derivatives and colloidal silica. The cellulose derivatives are selected from ethyl cellulose, hydroxypropylcellulose and methylcellulose, and mixtures and combination thereof (col. 4, lin.

65 – 67). The particles are wet granulated in a conventional solvent, and range in size from 10 – 1000 microns (col. 2, lin. 55 – 57). The coating can further include other polymers, which are added to the mixture along with Aerosil, a silica product (Examples). Also the temperature of the product of the reference ranges from 20 – 25 degrees Celsius. The reference however does not specify what type of solvent is used, and does not specify a particular pH requirement but specifies that it can be modified by addition components. The reference also does not disclose the specific ranges and concentrations as claimed by applicant.

'251 teaches dosage form comprising coated granules of ibuprofen. The granules are coated with cellulose derivatives and a silica product. The cellulose derivatives are selected from methylcellulose, hydroxypropylmethylcellulose, ethyl cellulose and other derivatives (claim 1). The particles are wet granulated with an alcoholic solvent (col. 5, lin. 42 – 51). Other excipients are added to the granule mixture including starches and other cellulose derivatives. The pH of the solution is maintained by a buffer at 7.5, yet can be modified to suit the needs of the dosage form (Examples). The reference also includes Aerosil in the coating of the granules.

3. Both references provide the theory to the coating of granulated ibuprofen with cellulose derivatives and silica products, yet the references are silent to the order in which they happen. Whether the granulation is first of the particles are coated and then granulated. '577 teaches a delayed release formulation of coated NSAID drugs, with cellulose ethers, and including taste masking sugars in the formulation (col. 10, lin. 7 – 19; col. 13 – 45).

With regard to the applicant's limitation that the granules include ibuprofen, its isomers and pharmaceutical salts thereof, it is the position of the examiner that these compounds are obvious variants of one another. It is obvious to a skilled artisan to include pharmaceutical salts

of an active agent in order to improve the bioavailability. Isomers of a compound are simply obvious variants, rearrangements of the original compound.

With regard to the ranges and concentrations recited by applicant, it is the position of the examiner that these limitations are merely recitations of the optimal workable ranges and do not impart patentability. The art presents the general theory of coating ibuprofen granules with cellulose derivatives and a silica product. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Also with respect to the order in which the method steps are carried out, it is the position of the examiner that the combined art obviates these limitations as well. The combination of the prior art would result in a similar product, having similar characteristics of the instant claims. Barring a showing of a functional difference between the products produced by the methods claimed invention. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to

prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

4. With these aspects in mind a skilled artisan would have been motivated to combine the teachings of the prior art. '577 provides the basic theory of taste masking NSAID formulations with sugars such as mannitol. A skilled artisan would be able to provide this to the formulation of '824 and '251 in order to provide an easier formulation to administer. A skilled artisan would have combined the solvent of '251 into the granule formulation of '824 in order to properly dissolve the excipients and provide a better coating medium. A skilled artisan would be able to maintain the pH of the product at a level suitable for the best application of the granules, dependent upon the administration. It would have been obvious to one of ordinary skill in the art to combine these teaches and suggestions with an expected result of micronized granule capable of being compressed into tablets with improved bioavailability.

Response to Arguments

5. Applicant's arguments with respect to claims 10-18, 20 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

Gollamudi S. Kishore, PhD
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Group 1600